REMARKS

I. Status of the Claims

Claims 17, 19-23, 26, 27, 29, 30, and 77-79 are currently pending and stand rejected. Claims 17, 23, and 26 are currently amended.

Claim 17 has been amended to specify that the material (i.e., combination of ingredients in the specified proportion of fine granules) is compression-molded "in order to provide intraorally rapidly disintegrable tablets." Support for the amendment may be found throughout the specification, *e.g.*, at p. 2, paragraph [0019]; p. 3, paragraph [0052]; and in the Abstract, of the published U.S. application (US 2005/0147666). Thus, no new matter has been added.

Claims 23 and 26 have been amended for formal reasons to specify that the material for compression molding "'further' contains a lubricant selected from the group ...." Because these amendments have been made for formal reasons only, no new matter has been added.

All claim amendments are made without prejudice or disclaimer. Applicants specifically reserve the right to file one or more continuation applications to pursue any subject matter removed from the claims by amendment.

By this Amendment, no new matter has been added to the application.

II. Claim Objections

The Examiner has objected to claims 23 and 26 for formal reasons. More specifically, the Examiner has requested that Applicants amend these claims to specify that the recited ingredients are "additionally" included in the "material for compression." Applicants have amended the claim according to the Examiner's suggestion, i.e., including the word "further" between "molding" and "contains." In light of the amendment, Applicants respectfully request this objection be withdrawn.

III. Rejection under 35 U.S.C. § 103(a)

A. Claims 17, 19-23, 26, 27, 30, and 77-79

The Examiner rejected claims 17, 19-23, 26, 27, 30, and 77-79 under 35 U.S.C. § 103(a) as being unpatentable over Lech et al, U.S. Patent No. 5,681,577 ("Lech") in view of Kutilek, III et al., U.S. Patent No. 5,770,217 ("Kutilek").

The Examiner contends that Lech teaches a method of making a cold/sinus preparation which comprises wet granulation of the active agents and an adsorbent, namely, silicon dioxide. The Examiner further contends that Lech teaches the adsorbent to comprise about 50% to about 85% of the adsorbable composition, which translates to a ratio of actives to adsorbate being approximately 1:10 to 1:1. The Examiner cites Example III, which teaches that the actives and adsorbents make up 25% (i.e., 1.25% + 3.0% + 20.75%) of the total weight of the preparation. Example III also teaches that, once the drug adsorbate is created, additional excipients including sweeteners, colorants, and flavorings are blended with the drug adsorbate, and then the particular lubricant, magnesium stearate, is added to the mixture and subsequently compressed into tablets. The Examiner further states that the actives taught by Lech are water-soluble, as evidenced by the step of dissolving the actives in water prior to the wet granulation step, and citing as a preferred active agent diphenhydramine HCl which has a solubility of 1g/1mL. The Examiner further states that Lech teaches incorporating particular excipients, including disintegrants such as microcrystalline cellulose and other cellulose derivatives in order to aid in the tabletting and oral administration processes, as well as including mannitol as a tabletting agent. The Examiner goes on to note that D-mannitol and mannitol are analogous, and that mannitol has a specific surface area of $0.60 m^2/g$ and has a particle-size distribution of between about 60 and 180 microns.

The Examiner concedes that Lech does not require a disintegrant, but contends that Lech provides motivation for including a disintegrant because Lech teaches that a disintegrant aids in the tabletting and oral administration processes.

The Examiner concedes that Lech is silent as to the incorporation of a lubricant on the surface of the punch and die, but relies on Kutilek to cure this deficiency. According to the Examiner, Kutilek teaches that lubricants are routinely employed in tabletting processes. The

Examiner also contends that Kutilek teaches application of lubricants to the tabletting tool surface, and the rationale for using lubricants, as well as the specific lubricants commonly used in the manufacture of tablets (and recited in the current claims). The Examiner also contends that Kutilek teaches the disintegrants recited in the current claims but not disclosed in Lech.

Finally, the Examiner acknowledges that Lech fails to teach the active ingredient recited in the claim 22, pravastatin sodium. However, according to the Examiner, Lech teaches how to create a tablet that reduces the bitter taste of active ingredients such as pravastatin sodium, so it would have been obvious to one of skill in the art to incorporate pravastatin sodium in the tablet taught by Lech.

Thus, according to the Examiner, it would have been obvious to one of ordinary skill in the art to add a lubricant and a disintegrant taught by Kutilek to the formulation taught by Lech, and further add the active ingredient pravastatin sodium, to arrive at the claimed invention.

Applicants respectfully traverse. The present invention relates to a process for **producing an intraorally rapidly disintegrable tablet**. More specifically, the sole independent claim (claim 17) as amended calls for a process that produces intraorally rapidly disintegrable tablets.

In order to establish a case of prima facie obviousness, the cited references must contain each and every element of the claimed invention. *See, e.g.* MPEP § 2143. Neither Lech nor Kutilek teach or suggest **production** of "**an intraorally rapidly disintegrable tablet**." Thus, a person skilled in the art would not be motivated to combine Lech and Kutilek to arrive at the claimed process for producing such a tablet.

More specifically, one of ordinary skill in the art, when seeking a process for making a rapidly disintegrable tablet, would not be motivated to combine the two references because there is no disclosure or suggestion of rapidly disintegrating tablets, much less a process for making rapidly disintegrating tablets. Put another way, a person of ordinary skill in the art, when seeking a process for making a rapidly disintegrable tablet, would not look to Lech or Kutilek, either alone or in combination, for guidance.

Moreover, Lech teaches away from a process for producing the rapidly disintegrable tablets of the present application. Lech teaches chewable formulations. There would be no reason to include the property of rapid intraoral disintegration in a chewable formulation. One of skill in the art, looking for a tablet that rapidly disintegrates, would not look for guidance to a reference that teaches a chewable formulation.

Kutilek also teaches away from a process for producing the rapidly disintegrable tablets. Kutilek teaches multiple dosage formulations, including tablets, capsules, powders and liquids. Three of these formulations would require no ingredient or combination of ingredients that would result in rapid disintegration. As with the chewable formulations taught by Lech, there would be no reason to include the property of rapid intraoral disintegration in liquid, powder or capsule formulations.

Claims 19-23, 26, 27, 30, and 77-79 depend from claim 17 and are not obvious over Lech and Kutilek for the same reasons as provided for claim 17.

Thus, claims 17, 19-23, 26, 27, 30, and 77-79 are not obvious over Lech and Kutilek and this obviousness rejection should be withdrawn.

B. Claim 29

Claim 29 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Lech in view of Kutilek and further in view of the Handbook for Pharmaceutical Excipients ("Handbook").

The Examiner cites Lech and Kutilek for the same reasons discussed above regarding claims 17, 19-23, 26, 27, 30, and 77-79. The Examiner acknowledges Lech is silent as to the weight percentage range of D-mannitol being 20-99% of the tablet. The Examiner relies on the Handbook to cure this deficiency. More specifically, the Examiner contends that the Handbook teaches that mannitol is typically used in amounts of 10-90% in conventional tabletting. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to include mannitol in the amounts suggested by the Handbook with a reasonable expectation of success because the prior art suggests that mannitol is routinely and traditionally used in tablets in the amount of 10-90%.

Applicants respectfully traverse. Applicants note that claim 29 depends from claim 17. As discussed above, claim 17 is not obvious over Lech in view of Kutilek because neither Lech nor Kutilek teach or suggest a process for producing an intraorally rapidly disintegrable tablet. Applicants note that the Handbook does not teach such a process, either. Because the Handbook does not teach or suggest a process for producing an intraorally rapidly disintegrable tablet, it cannot cure the defects in the obviousness rejection over Lech and Kutilek. Thus, claim 29 is not obvious over Lech in view of Kutilek and the Handbook for the same reasons as claims 17, 19-23, 26, 27, 30, and 77-79 are not obvious over Lech and Kutilek, and this obviousness rejection should be withdrawn.

C. Claims 19 and 77-79

Claims 19 and 77-79 stand rejected under 35 U.S.C. 103(a) for obviousness over Lech in view of Kutilek and further in view of Remington: The Science and Practice of Pharmacy. ("Remington").

The Examiner cites Lech and Kutilek for the same reasons discussed above regarding claims 17, 19-23, 26, 27, 30, and 77-79. The Examiner acknowledges that Lech and Kutilek are silent as to the disintegrants crospovidone, low-substituted hydroxypropyl cellulose and croscarmellose sodium recited in the rejected claims. The Examiner relies on Remington to cure these deficiencies by teaching these elements of the claims. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to substitute the disintegrants taught in Remington for those taught in Lech and Kutilek because such disintegrants are "art-recognized equivalents" of one another. According to the Examiner, such "substitution would achieve the predictable result of producing a tablet."

Applicants respectfully traverse for the same reason as provided above. Claims 19 and 77-79 ultimately depend from claim 17. As discussed above, neither Lech nor Kutilek teach or suggest a process for producing an intraorally rapidly disintegrable tablet. Applicants note that Remington does not teach such a process, either. And, because Remington does not teach or suggest a process for producing an intraorally rapidly disintegrable tablet, it cannot cure the defects in the obviousness

rejection over Lech and Kutilek. Thus, claims 19 and 77-79 are not obvious over Lech in view of Kutilek and Remington for the same reasons as claims 17, 19-23, 26, 27, 30, and 77-79 are not obvious over Lech and Kutilek, and this obviousness rejection should be withdrawn.

III. CONCLUSION

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

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